

MEDICATION GUIDE

Sodium Sulfate (soe’ dee um sul’ fate),
Potassium Sulfate (poe tas’ ee um sul’ fate)
and Magnesium Sulfate
(mag nee’ zee um sul’ fate) Oral Solution

Read and understand this Medication Guide instructions **at least 2 days before** your colonoscopy and again before you start taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

What is the most important information I should know about Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution and other bowel preparations can cause serious side effects, including:

- **Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes can cause:**
- **abnormal heartbeats that can cause death**
 - **seizures.** This can happen even if you have never had a seizure.
 - **kidney problems**

Your chance of having fluid loss and changes in body salts with Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution is higher if you:

- have heart problems
- have kidney problems
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution:

- vomiting
- dizziness
- urinating less often than normal
- headache

See “What are the possible side effects of sodium sulfate, potassium sulfate and magnesium sulfate oral solution?” for more information about side effects.

What is Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution is a prescription medicine used by adults to clean the colon before a colonoscopy. Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

It is not known if Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution is safe and effective in children under 12 years of age.

Do not take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution if your healthcare provider has told you that you have:

- a blockage in your intestine (bowel obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- a very dilated intestine (toxic megacolon)
- problems with the emptying of food and fluid from your stomach (gastric retention)
- an allergy to any of the ingredients in Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution. See the end of this Medication Guide for a complete list of ingredients in Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

Before taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution, tell your healthcare provider about all of your medical conditions, including if you:

- have problems with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).
- have gout
- have heart problems including an irregular heartbeat, especially a condition called “QT prolongation”.
- have a history of seizures or take medicines for seizures.
- are withdrawing from drinking alcohol or from taking benzodiazepines.
- have a low blood salt (sodium) level.
- have kidney problems or take medicines for kidney problems.
- have stomach or bowel problems including ulcerative colitis.
- have problems with swallowing or gastric reflux.
- are pregnant or plan to become pregnant. It is not known if Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution will harm your unborn baby. Talk to your healthcare provider if you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution passes into your breast milk. You and your healthcare provider should decide if you will take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of each dose of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems.
- medicines for kidney problems.
- medicines for seizures.
- water pills (diuretics).
- non-steroidal anti-inflammatory medicines (pain medicines).
- medicines for depression or mental health problems.
- laxatives. **Do not** take other laxatives while taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

The following medicines should be taken at least 2 hours before starting Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution and not less than 6 hours after taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution:

- tetracycline
- fluoroquinolone antibiotics
- iron
- digoxin (Lanoxin)
- chloropromazine
- penicillamine (Cuprimine. Depen)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?

See the Instructions for Use in the Patient Instructions for Use Carton for dosing instructions. You must read, understand, and follow these instructions to take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution the right way.

- Take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution exactly as your healthcare provider tells you to take it.

210 x 297 mm

Front page

NOTE: Artwork is prepared for Electronic Medication Guide Purpose - Not to be printed.

ARTWORK DETAIL LABEL					
Product	Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5 g/3.13 g/1.6 g				
Buyer/Country	STRIDES PHARMA INC - US	Component	Electronic Medication Guide		
Dimension	210 x 297 mm			Pack	--
New Item Code	1052602	Old Item Code	1042110		
Colour Shades	 BLACK			No. of Colours	1
Change Control No.	PC-ODF/2025/408 - Record Number: 460262 & PC-TSG/2025/052 - Record Number: 463027			Artwork Version	2.0
Design/Style	NA				
Substrate	NA				
Special Instructions	NA				
Autocartonator Requirements	NA				
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.					
RD/PD/003/F-08/R					

- Each bottle of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution must be mixed with water (diluted) before drinking.
- It is important for you to drink the additional prescribed amount of water listed in the Instructions for Use to prevent fluid loss (dehydration).
- One bottle of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution is equal to one dose.
- Two doses of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution are required for complete colonoscopy preparation.
- All people taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution should follow these general instructions starting 1 day **before** your colonoscopy:
 - eat only a light breakfast or clear liquids (for example: water, strained fruit juice without pulp, lemonade, plain coffee or tea, chicken broth, gelatin dessert without fruit) on the day before your procedure.
 - only drink clear liquids the rest of the day and the next day until 2 hours before your colonoscopy. **Stop** drinking all fluids at least 2 hours before your colonoscopy.
 - after taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution if you have any bloating or feeling like your stomach is upset, wait to take your second dose until your stomach feels better.
- **While taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution, do not:**
 - take any other laxatives.
 - take any medicines by mouth (oral) within 1 hour of starting Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.
 - eat solid foods, drink dairy (such as milk), or drink alcohol while taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution and until after your colonoscopy
 - eat or drink anything colored red or purple.

Contact your healthcare provider right away if after taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution you have severe vomiting, signs of dehydration, changes in consciousness such as feeling confused, delirious or fainting (loss of consciousness) or seizures after taking Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

What are the possible side effects of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution can cause serious side effects, including:

- See **“What is the most important information I should know about Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?”**
- **Changes in certain blood tests.** Your healthcare provider may do blood tests after you take Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach area (abdomen) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
 - trouble swallowing
 - seizures
 - heart problems
 - worsening gout

- **Ulcers of the bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution in adults include:

- overall discomfort
- stomach bloating
- stomach pain
- nausea
- vomiting

These are not all the possible side effects of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?

- Store Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution and all medicines out of the reach of children.

General information about the safe and effective use of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution for a condition for which it was not prescribed. Do not give Sodium Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution to other people, even if they are going to have the same procedure you are. It may harm them. You can ask your pharmacist or healthcare provider for information about Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution that is written for healthcare professionals.

What are the ingredients in Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution?

Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution is supplied in two dosage strengths. Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution comes in a carton containing two 6-ounce bottles, along with a 16-ounce polypropylene mixing container.

Each bottle contains:

Active ingredients: sodium sulfate, potassium sulfate and magnesium sulfate.

Inactive ingredients: citric acid monohydrate USP, mixberry flavor, malic acid USP-NF, purified water, sodium benzoate USP-NF, sucralose USP-NF.

Manufactured by:
Strides Pharma Science Limited
Bengaluru – 562106, India.

Distributed by:
Strides Pharma Inc.
Bridgewater, NJ 08807.

For more information, call Strides Pharma Inc. at 1-877-244-9825.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 09/2025

1052602

210 x 297 mm

Back page

NOTE: Artwork is prepared for Electronic Medication Guide Purpose - Not to be printed.

ARTWORK DETAIL LABEL

Product	Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5 g/3.13 g/1.6 g					
Buyer/Country	STRIDES PHARMA INC - US		Component	Electronic Medication Guide		
Dimension	210 x 297 mm				Pack	--
New Item Code	1052602		Old Item Code	1042110		
Colour Shades	 BLACK				No. of Colours	1
Change Control No.	PC-ODF/2025/408 - Record Number: 460262 & PC-TSG/2025/052 - Record Number: 463027				Artwork Version	2.0
Design/Style	NA					
Substrate	NA					
Special Instructions	NA					
Autocartonator Requirements	NA					
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.						